



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Kevin J. Tracey and Haichao Wang  
Application No.: 10/719,150 Group Art Unit: 3754  
Filed: November 21, 2003 Examiner: Not Yet Assigned  
Confirmation No.: 3380  
Title: ANTAGONISTS OF HMG1 FOR TREATING INFLAMMATORY CONDITIONS

| CERTIFICATE OF MAILING OR TRANSMISSION  |                                    |
|---|------------------------------------|
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on: |                                    |
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| <u>Donna Boudreau</u><br>Typed or printed name of person signing certificate  |                                    |

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
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Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references are enclosed (AD, AQ, AW5-AZ5, AR6-AZ6 and AR7).
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By David E. Brook  
David E. Brook  
Registration No.: 22,592  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: 10/14/04

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|---|--|--------------------------------------|--|-------------------------------|--|
| PTO-1449 REPRODUCED   |  | ATTORNEY DOCKET NO.<br>3268.1000-012 |  | APPLICATION NO.<br>10/719,150 |  |
| <b>SUPPLEMENTAL INFORMATION DISCLOSURE<br/>CITATION IN AN APPLICATION</b><br><br><b>September 23, 2004</b><br>(Use several sheets if necessary) |  |                                      |  | FILING DATE<br>11/21/2003     |  |
|   |  |                                      |  | GROUP<br>3754                 |  |
| FIRST NAMED INVENTOR<br>Kevin J. Tracey   |  |                                      |  | CONFIRMATION NO.<br>3380      |  |
| EXAMINER  |  |                                      |  |                               |  |

### U.S. PATENT DOCUMENTS

| EXAM-<br>INER<br>INI-<br>TIAL | REF.<br>NO. | DOCUMENT NUMBER<br>Number-Kind Code (if known) | ISSUE DATE /<br>PUBLICATION DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT |
|-------------------------------|-------------|--|--|--|
|                               | AD          | 5,594,114                                      | 01-14-1997                                     | Goodearl, A. D. J., <i>et al.</i>                  |

### FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER<br>Country Code-Number-Kind Code<br>(if known) | DATE<br>MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT<br>OF CITED DOCUMENT | TRANSLATION<br>YES NO |
|--|----|--|--------------------|--|-----------------------|
|  | AQ | WO 2004/004763 A2  | 01-15-2004         | Bianchi, M. E., <i>et al.</i>                      |                       |

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |     |   |
|--|-----|---|
|  | AW5 | Bustin, M., <i>et al.</i> , "Immunological Relatedness of High Mobility Group Chromosomal Proteins from Calf Thymus," <i>J. Biol. Chem.</i> , 253(5):1694-1699 (1978).  |
|  | AX5 | Rauvala, H. and Pihlaskari, R., "Isolation and Some Characteristics of an Adhesive Factor of Brain That Enhances Neurite Outgrowth in Central Neurons," <i>J. Biol. Chem.</i> , 262(34):16625-16635 (1987).   |
|  | AYS | Daston, M. M. and Ratner, N., "Expression of P30, a Protein with Adhesive Properties, in Schwann Cells and Neurons of the Developing and Regenerating Peripheral Nerve," <i>J. Cell Biol.</i> , 112(6):1229-1239 (1991).                                |
|  | AZ5 | Parkkinen, J., <i>et al.</i> , "Amphoterin, the 30-kDa Protein in a Family of HMG1-type Polypeptides," <i>J. Biol. Chem.</i> , 268(26):19726-19738 (1993).  |
|  | AR6 | Sobajima, J., <i>et al.</i> , "High Mobility Group (HMG) Non-Histone Chromosomal Proteins HMG1 and HMG2 are Significant Target Antigens of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies in Autoimmune Hepatitis," <i>Gut</i> , 44:867-873 (1999). |
|  | AS6 | Ma W., <i>et al.</i> , "Detection of Anti-Neutrophil Cytoplasmic Antibodies in MRL/Mp- <i>lpr/lpr</i> Mice and Analysis of Their Target Antigens," <i>Autoimmunity</i> , 32(4):281-291 (2000).  |
|  | AT6 | Banks, G. C., <i>et al.</i> , "The HMG-I(Y) A-T-hook Peptide Motif Confers DNA-binding Specificity to a Structured Chimeric Protein," <i>J. Biol. Chem.</i> , 274(23):16536-16544 (1999).   |

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| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

3268.1000-012

10/719,150

SUPPLEMENTAL INFORMATION DISCLOSURE  
CITATION IN AN APPLICATION

September 23, 2004

(Use several sheets if necessary)

FIRST NAMED INVENTOR

Kevin J. Tracey

FILING DATE

11/21/2003

EXAMINER

CONFIRMATION NO.

3380

GROUP

3754

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|     |  |
|-----|--|
| AU6 | Scaffidi, P., <i>et al.</i> , "Release of Chromatin Protein HMGB1 by Necrotic Cells Triggers Inflammation," <i>Nature</i> , 418:191-195 (2002).  |
| AV6 | Abaza, M.-S. I. and Atassi, M. Z., "Effects of Amino Acid Substitutions Outside an Antigenic Site on Protein Binding to Monoclonal Antibodies of Predetermined Specificity Obtained by Peptide Immunization: Demonstration with Region 94-100 (Antigenic Site 3) of Myoglobin," <i>J. Protein Chem.</i> , 11(5):433-444 (1992).  |
| AW6 | Colman, P. M., "Effects of Amino Acid Sequence Changes on Antibody-Antigen Interactions," <i>Res. Immunol.</i> , 145(1):33-36 (1994).  |
| AX6 | Freeman, B. D., <i>et al.</i> , "The Role of Inflammation in Sepsis and Septic Shock: A Meta-Analysis of Both Clinical and Preclinical Trials of Anti-Inflammatory Therapies," in <i>Inflammation: Basic Principles and Clinical Correlates</i> (John I. Gallin and Ralph Snyderman eds., Lippincott, Williams & Wilkins, Philadelphia, 3 <sup>rd</sup> ed. 1999), pp 965-975. |
| AY6 | Lederman, S., <i>et al.</i> , "A Single Amino Acid Substitution in a Common African Allele of the CD4 Molecule Ablates Binding of the Monoclonal Antibody OKT," <i>Mol. Immunol.</i> , 28(11):1171-1181 (1991).  |
| AZ6 | Czura, C., <i>et al.</i> , "Dual Roles for HMGB1: DNA Binding and Cytokine," <i>J. Endotoxin Res.</i> , 7(4):315-321 (2001).   |
| AR7 | Wen, L., <i>et al.</i> , "A Human Placental cDNA Clone that Encodes Nonhistone Chromosomal Protein HMG-1," <i>Nucleic Acids Res.</i> , 17(3):1197-1213 (1989).   |

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DATE CONSIDERED